

**REMARKS**

In the Office Action dated November 27, 2007, claims 1, 2, 4, 8-10, 12 and 14-17, in the above-identified U.S. patent application were rejected. Reconsideration of the rejections is respectfully requested in view of the above amendments and the following remarks. Claims 1, 2, 4, 8-10, 12 and 14-17 remain in this application, claims 3, 5-7, 11, and 13 have been canceled previously or in the present response and new claim 18 has been added to the application. New claim 18 does not raise new issues as the limitations in new claim 18 are also recited in claims 8 and 14.

Claims 1, 2, 4, 8-10, 12 and 14-17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Bleumer et al. (January 2002, European Urology Supplements, Vol. 1, No. 1, pp. 112) in view of Pavone et al. (2001, Cancer Immunol. Immunother. 50:82-86). Enclosed with this response is a declaration presenting data regarding the co-administration of an anti-tumor antibody directed against the MN antigen and a cytokine which is an interferon. As discussed in the declaration, co-administration of an antitumor antibody (e.g. G250) and interferon (e.g. interferon- $\alpha$ ) leads to an increased efficacy in the treatment of renal cell carcinoma as compared to administration of either G250 or interferon- $\alpha$  alone along with a reduction in side effects. The increased efficacy is due to a synergistic effect from the co-administration of the anti-tumor antibody and an interferon. This synergistic effect could not have been predicted from the disclosure in Bleumer which discloses only a monotherapy for treating RCC using the G250 antibody.

Regarding Bleumer's pretreatment of patients with IL-2, the enclosed declaration indicates that if the pretreatment with IL-2 had been efficacious, then the G250 antibody

would not have been administered. In addition, applicants contend that if Bleumer had expected the IL-2 to be efficacious, it would not have been considered a "pretreatment" prior to the administration of the G250 antibody. Since the purpose of Bleumer's study was to test the treatment of RCC with G250, IL-2 would not have been administered first if it was expected to be efficacious. Pavone does not cure the deficiencies in Bleumer because Pavone does not disclose a synergistic effect either. Pavone teaches that IL-2 and IL- $\alpha$  have produced good results but does not suggest the combination of G250 and IL-2 or IL- $\alpha$ . Applicants respectfully submit that one skilled in the art would not combine the disclosures of Bleumer and Pavone to arrive at the combined, simultaneous treatment required by the present claims because a skilled artisan is aware of the intractability of RCC to therapy and a skilled artisan would not have expected interferon- $\alpha$  to be efficacious in treating RCC. In view of the fact that neither Bleumer nor Pavone, individually or in combination suggest that co-administration of an antitumor antibody (e.g. G250) and interferon (e.g. interferon- $\alpha$ ) will have increased efficacy and reduced side effects, applicants request that this rejection be withdrawn.

Applicants respectfully submit that all of claims 1, 2, 4, 8-10, 12 and 14-17 are now in condition for allowance. If it is believed that the application is not in condition for allowance, it is respectfully requested that the undersigned attorney be contacted at the telephone number below.

In the event this paper is not considered to be timely filed, the Applicant respectfully petitions for an appropriate extension of time. Any fee for such an extension together with any additional fees that may be due with respect to this paper, may be charged to Counsel's Deposit Account No. 02-2135.

Respectfully submitted,

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